

PARTIES

4. Plaintiff, the State of Vermont, through William H. Sorrell, Attorney General, is charged, inter alia, with the enforcement of the Vermont Consumer Fraud Act, 9 V.S.A §§ 2451-66.

5. AstraZeneca Pharmaceuticals, LP and AstraZeneca LP are the Defendants in this case. AstraZeneca's Corporate Headquarters are located at 1800 Concord Pike, Wilmington, DE 19850-5437. AstraZeneca transacts business in Vermont and nationwide by manufacturing, marketing, promoting, selling and distributing prescription drugs, including Seroquel.

BACKGROUND

6. AstraZeneca manufactures, markets, and promotes Seroquel nationally and in Vermont. Seroquel is a drug classified as an atypical antipsychotic.

7. While some experts hypothesized, as early as 1993, that atypical antipsychotics may reduce some of the side effects that traditional antipsychotics cause, there were early signs that these drugs, including Seroquel, produced dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications and other severe conditions.

8. Seroquel received approval from the U.S. Food and Drug Administration ("FDA"), for the treatment of manifestations of psychotic disorders, including schizophrenia, on September 26, 1997.

9. The FDA narrowed Seroquel's label to "indicated for the treatment of schizophrenia" on March 27, 2001.

ASTRAZENECA'S MARKETING OF SEROQUEL

10. Vermont permits physicians to prescribe FDA-approved drugs for conditions or diseases for which FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines the drug in question is an appropriate treatment for an individual patient. This practice is referred to as "off-label prescribing."

11. However, pharmaceutical manufacturers may not promote or market their products for any use not specifically approved by the FDA. This prohibited practice is known as "off-label marketing."

12. Before late 2009, Seroquel was approved by the FDA only for the treatment of certain specific conditions in adults, primarily conditions related to Schizophrenia and Bipolar Mania.

13. Despite having narrow FDA approval for adults only, AstraZeneca promoted and marketed the drug for the treatment of a variety of conditions and to a variety of patient populations not included among the FDA-approved indications, including for anxiety, depression and post traumatic stress disorder, and to child and geriatric populations.

14. Through this off-label marketing, AstraZeneca aimed to enhance Seroquel's market penetration across a wide range of diagnoses and patient populations.

15. AstraZeneca promoted Seroquel's use in children and adolescents long before establishing with the FDA that it was safe or effective for any use in this population.

16. AstraZeneca promoted Seroquel to treat dementia and Alzheimer's disease in the elderly even though Seroquel has never been approved for the treatment of these conditions and AstraZeneca has not established that Seroquel is safe and effective for these

uses.

17. AstraZeneca also masked, withheld, or failed to disclose negative information contained in scientific studies concerning the safety and efficacy of Seroquel.

18. AstraZeneca failed to adequately disclose the risks associated with Seroquel's use by, among other things, minimizing the risk of hyperglycemia and diabetes mellitus and failing to communicate important information regarding neuroleptic malignant syndrome, tardive dyskinesia, and the risk of bolded cataracts.

VIOLATIONS OF LAW

19. Paragraphs 1-18 of this complaint are incorporated herein as though set forth in full. 9 V.S.A. § 2458(a) authorizes the Attorney General to bring an action to enjoin Defendants from engaging in a method, act, or practice that is in violation of the Vermont Consumer Fraud Act, 9 V.S.A. §§ 2451-66.

20. All of the acts and practices engaged in and employed by the Defendants as alleged herein, are unfair or deceptive acts or practices affecting the conduct of any trade or commerce in Vermont, in violation of the Vermont Consumer Fraud Act, 9 V.S.A. §§ 2451-66.

21. By promoting Seroquel for uses that have not been shown to be safe or effective and by failing to adequately disclose the risks associated with Seroquel's use, the Defendants have violated the Vermont Consumer Fraud Act, 9 V.S.A. §§ 2451-66.

PRAYER FOR RELIEF

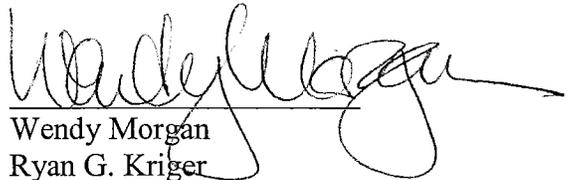
WHEREFORE, the Plaintiff prays that this honorable Court enter an Order:

- A. Issuing a permanent injunction prohibiting Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive conduct;
- B. Ordering Defendants to pay all costs for the prosecution and investigation of this action, as provided by 9 V.S.A. § 2458(b)(3);
- C. Ordering Defendants to pay civil penalties of \$10,000.00 pursuant to 9 V.S.A. § 2458(b)(1) for each and every violation of the Vermont Consumer Fraud Act, 9 V.S.A. §§ 2451-66; and
- D. Granting such other and further relief as the Court deems equitable and proper.

Dated March 10, 2011.

Respectfully submitted,

WILLIAM H. SORRELL
ATTORNEY GENERAL
STATE OF VERMONT



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